REMARKS

New claims 21-30 are in this case for consideration. Claims 1-10 have been withdrawn due to the Examiner's restriction requirement and claims 11-21 have been canceled, without prejudice, to expedite prosecution.

A. Prior Art Rejections

1. The Invention

Applicant has invented a method of posterior arthroplasty for replacing damaged vertebral discs. Unlike existing anterior arthroplasty, permanently articulating vertebral implant devices are inserted using Applicant's method through a minimally invasive posterior incision near the site of the damaged vertebral disc. After the incision is made in Applicant's process, a partial discectomy is posteriorly performed to remove damaged fibrocartilage disc tissue. After the discectomy, at least two permanently articulating vertebral implant devices are posteriorly inserted to replace disc tissue in a way which approximates the disc's natural flexion. To avoid damage to spinal nerve tissue and provide necessary balance, at least one vertebral implant device is inserted on each side of a vertical medial plane defined by the spinous processes of the superior and inferior vertebrae.

2. The Cited Art Distinguished

Applicant's former claims 15 and 17-20 have been rejected under 35 U.S.C. § 103(a) as being obvious over Bullivant's U.S. Patent No. 5,507,816 ("Bullivant patent") in view of Peckett's "Hartshill Horseshoe" article ("Peckett article").

The Bullivant patent discloses a "ball and socket" type vertebral implant device which can be placed, by itself, between two vertebrae to replace a damaged disc.

The Peckett article discloses a small horseshoe shaped device constructed of bone tissue or titanium which can be used to help fuse two vertebrae together. The Peckett article discusses that fusion operations can be performed using either anterior or posterior approaches.

Both the Peckett article and Bullivant patent teach away from Applicant's invention. First, as previously noted, the Peckett article pertains to methods of *fusing* two vertebrae together. During fusion surgery, the discectomy of the damaged disc is often followed by insertion of a lattice matrix between the vertebrae, such as a bonelike horseshoe, which helps the adjacent vertebrae to grow or "fuse" together into one piece. The whole purpose of a fusion operation is thus to *prevent* the vertebrae from being able to articulate relative to one another.

As an alternative to fusion surgery, articulating devices like Bullivant's "ball and socket" implant were known in the art, but, because of their size, had to be inserted anteriorly between the vertebrae. Anterior insertion means that, in the case of a lumbar disc replacement, an incision is made near the patient's navel and many of the patient's bodily organs (e.g., intestines etc.) need to be moved aside before the surgeon can gain access to the damaged vertebral disc. Using the anterior approach, the surgery is conducted perilously close to major

arteries and veins. If the surgeon makes a mistake by cutting such arteries or veins during the anterior spine surgery, the patient can easily die by bleeding to death.

While a posterior approach was previously known for fusion surgery, it was thought to be unavailable for arthroplasty (i.e., the insertion of articulating implant devices) because the existing articulating implant devices were too large to fit around the complicated arrangement of bones (e.g., the spinous processes, articulated processes, facet joints, lamina etc.) protecting access to the damaged disc from the posterior direction. Moreover, even if many of these bones could be removed during surgery, there was still the problem of working around the spinal cord and/or spinal nerve roots blocking access to the damaged disc from the posterior direction.

While fusion devices could be made small enough to work around these posterior direction obstacles, the same was thought not to be true for articulating implant devices. It was thought that articulating implant devices needed to provide a full range of rotational motion, like the "ball and socket" implant device disclosed in the Bullivant patent, in order to be a suitable disc replacement. Since such fully rotational implant devices were too large for posterior insertion, they needed to be inserted anteriorly.

Applicant's breakthrough began with his recognition that the conventional wisdom about needing a full range of rotational motion, as illustrated in the Bullivant patent, was, in many cases, wrong. Applicant observed that in the lumbar region, for example, the facet joints naturally found in the human body act as a type of doorstep to *prevent* full rotational movement. Applicant reasoned that if full rotational movement was not necessary, articulating implant devices could be made smaller and inserted in a way which would inhibit rotational

movement. Because of all the bone and nerve obstacles to such a posterior insertion, Applicant further reasoned that it would be best to insert two smaller articulating implant devices around the left and right sides, respectively, of the spinal cord/spinal nerve roots so that there would be an articulating vertebral implant device on each side of the vertical medial plane defined by the spinous process of the superior and inferior vertebrae. By implanting two articulating implant devices in this way, the implant devices could provide support for each side of the spine (i.e., both the left and right sides) and the resulting resistance to rotational movement of the two devices acting together would simulate the body's own resistance through facet joints. As such, Applicant's invention provided a less invasive, less dangerous surgery and more faithfully replaced the damaged disc, at least in the lumbar region, than either the "ball and socket" type anterior implant devices (e.g., the Bullivant patent) or the existing fusion technology (e.g., the Peckett article). Since the Bullivant patent and Peckett article both teach away from Applicant's invention, neither the Bullivant patent nor the Peckett article, either alone or in combination, would render any of Applicant's presently pending claims obvious.

Applicant's former remaining claims 11-14 and 16 have been rejected under 35 U.S.C. § 103(a) as being unpatentably obvious over the Bullivant patent, the Peckett article and various combinations of Wong's "Paired Cylindrical Interbody Cage Fit" article ("Wong article"), Beer's U.S. Patent No. 4,458,642 ("Beer patent"), Gauchet's U.S. Patent No. 6,579,320 ("Gauchet patent") and Paes' U.S. Patent No. 6,436,142 ("Paes patent").

The Wong articles discloses that two cylindrical cages which can be inserted posteriorly in vertebral fusion surgery. As with the Peckett article, the purpose of the Wong cylinders is to help the vertebrae fuse together so that relative movement between the vertebrae

can be prevented. Since the Wong cylinders are designed in the shape of "cages", the vertebral bone will grow through the Wong cylinders during the course of healing so that no articulating movement will be possible.

The Beer patent discloses a single articulating vertebral implant device. There is no teaching or suggestion in the Beer patent that Beer's implant device could be inserted posteriorly or that two such devices should be placed on each side of a vertical medial plane defined by the spinous processes of the superior and inferior vertebrae.

The Gauchet patent discloses a single intervertebral disc prosthesis consisting of an elastomeric body held between two plates. Again there is no teaching of suggestion in the Gauchet patent of a posterior insertion method or that two such devices should be placed on each side of a vertical medial plane defined by the spinous processes of the superior and inferior vertebrae.

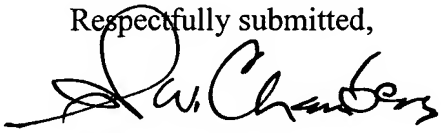
The Paes patent discloses a screw and shell form of vertebral implant device. As shown in Fig. 9 of the Paes patent, a single Paes implant is inserted between vertebrae from the anterior direction.

Since neither the Bullivant patent, Peckett article, Wong article, Beer patent, Gauchet patent or Paes patent, either alone or in any combination, discloses Applicant's invention of a method for posterior insertion of a pair of permanently articulating vertebral implant devices placed on each side of a vertical medial plane defined by the spinous process of the superior and inferior vertebrae, none of the cited references would render any of Applicant's presently pending claims unpatentable.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (415) 576-0200.

Respectfully submitted,



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